

**PATENT COOPERATION TREATY**

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>P2130 PCT</b>	<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416
International application No. <b>PCT/CH2004/000474</b>	International filing date ( <i>day/month/year</i> ) <b>29.07.2004</b>	Priority date ( <i>day/month/year</i> ) <b>31.07.2003</b>
International Patent Classification (IPC) or national classification and IPC <b>A61B17/02, A61N7/00, A61F2/46, A61B17/88, B06B3/00, A61C1/07, A61C8/00</b>		
Applicant <b>WOODWELDING AG</b>		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☒ (sent to the applicant and to the International Bureau) a total of 7 sheets, as follows:

☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/CH2004/000474

Box No. I	Basis of the report
1.	<p>With regard to the <b>language</b>, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.</p> <p><input type="checkbox"/> This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:</p> <p><input type="checkbox"/> international search (Rule 12.3 and 23.1(b))</p> <p><input type="checkbox"/> publication of the international application (Rule 12.4)</p> <p><input type="checkbox"/> international preliminary examination (Rule 55.2 and/or 55.3)</p> <p>2. With regard to the <b>elements</b> of the international application, this report is based on <i>(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)</i>:</p> <p><input type="checkbox"/> the international application as originally filed/furnished</p> <p><input checked="" type="checkbox"/> the description:</p> <p>pages <u>1-20</u> _____ as originally filed/furnished</p> <p>pages* _____ received by this Authority on _____</p> <p>pages* _____ received by this Authority on _____</p> <p><input checked="" type="checkbox"/> the claims:</p> <p>nos. _____ as originally filed/furnished</p> <p>nos.* _____ as amended (together with any statement) under Article 19</p> <p>nos.* <u>1-25</u> _____ received by this Authority on <u>30.05.2005 with letter</u></p> <p>nos.* _____ received by this Authority on <u>of 30.05.2005</u></p> <p><input checked="" type="checkbox"/> the drawings:</p> <p>sheets <u>1/5-5/5</u> _____ as originally filed/furnished</p> <p>sheets* _____ received by this Authority on _____</p> <p>sheets* _____ received by this Authority on _____</p> <p><input type="checkbox"/> a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.</p> <p>3. <input type="checkbox"/> The amendments have resulted in the cancellation of:</p> <p><input type="checkbox"/> the description, pages _____</p> <p><input type="checkbox"/> the claims, nos. _____</p> <p><input type="checkbox"/> the drawings, sheets/figs _____</p> <p><input type="checkbox"/> the sequence listing (specify): _____</p> <p><input type="checkbox"/> any table(s) related to sequence listing (specify): _____</p> <p>4. <input type="checkbox"/> This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).</p> <p><input type="checkbox"/> the description, pages _____</p> <p><input type="checkbox"/> the claims, nos. _____</p> <p><input type="checkbox"/> the drawings, sheets/figs _____</p> <p><input type="checkbox"/> the sequence listing (specify): _____</p> <p><input type="checkbox"/> any table(s) related to sequence listing (specify): _____</p>

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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## Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1-11

because:

☐ the said international application, or the said claims Nos. \_\_\_\_\_  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1-11

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☒ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
  - ☒ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ neither restricted the claims nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
  - ☒ not complied with for the following reasons:

The different inventions or groups of inventions are as follows:

Claims 12-18:

Device with a vibration source and an amplitude and/or direction-changing element.

Claims 19-25:

Treatment instrument with distal contact surfaces having energy flow guides.

For the following reasons, these inventions or groups of inventions are not so linked as to form a single general inventive concept (PCT Rule 13.1):

The common features of claims 12, 17 and 19, 21 are as follows: a device for promoting tissue regeneration using a treatment instrument and a vibration source.

4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
  - ☐ the parts relating to claims Nos. \_\_\_\_\_

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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## 1. Statement

Novelty (N)	Claims	16-25	YES
	Claims	12-15	NO
Inventive step (IS)	Claims	16-18	YES
	Claims	12-15, 19-25	NO
Industrial applicability (IA)	Claims	12-25	YES
	Claims		NO

## 2. Citations and explanations (Rule 70.7)

Invention I

1. **US-A-5885301 (D1)** already discloses (see figure 1):

a device suitable for promoting tissue generation on wound surfaces, the device having a vibration source 20 and a treatment instrument 19 that can be set into vibration by the vibration source. Since the ring 10 in D1 is an amplitude/direction changing element with a plurality of connecting points 30 (see figure 6), it is also suitable for being connected in different positions to only one vibration source.

Therefore, D1 discloses all of the features of claim 12.

2. Dependent claims 13-15 contain no features that, in combination with the features of any claim to which they refer, meet the PCT requirements for novelty and inventive step:

- claim 13: D1 already discloses a flat coupling surface (figure 1),

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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- claims 14 and 15: see D1.

3. **US-A-5426341 (D2)** discloses (see figure 4) a direction-changing element with a treatment instrument 6 and an opposing opening. It is not obvious to combine D1 and D2 and also to rotate the instrument in D2 such that it protrudes from the element through the opposing opening. The purpose of the opening in D2 is merely to screw in the sonotrode.

Therefore, the features of claim 16 meet the PCT requirements for novelty and inventive step.

4. **US-A-5426341 (D2)** discloses a direction-changing element with a treatment instrument 6 and an opposing opening. It is not obvious to combine D1 and D2 and also to rotate the instrument in D2 in order to render the device more compact such that it protrudes from the element through the opposing opening. The purpose of the opening in D2 is merely to screw in the sonotrode.

Therefore, the features of claim 17 meet the PCT requirements for novelty and inventive step.

Claim 18 is dependent on claim 17 and therefore likewise meets the PCT requirements for novelty and inventive step.

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statementInvention II

1. **US-A-5456686 (D5)** already discloses (see figures 4 and 5):

a treatment instrument 36 or implant embodied in the form of a vibrating body, its proximal end having a coupling surface 39, and contact surfaces (see figure 5) with energy flow guides being located in the area of the distal end.

A person skilled in the art would exchange the rasp for a rasp having tips or edges arranged at a distance of 2 to 5 mm from each other, without thereby being inventive. Such rasps are known from the prior art; see, for example, **US-A-4601289 (D6)**.

Therefore, the features of claims 19, 21 and 22 do not meet the PCT requirements for novelty and inventive step.

2. Dependent claims 20 and 22-25 contain no features that, in combination with the features of any claim to which they refer, meet the PCT requirements for novelty and inventive step:

- Claims 20 and 23: D6 already discloses a rasp with grooved edges, and axially extending edges are already known from **FR-A-2610819 (D3)**.

- Claims 24 and 25: a person skilled in the art would consider it a matter of standard practice to apply grooved edges to the implant known from **FR-A-**

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

**2808183 (D4)**, which has a proximal end la suitable  
for connecting to a vibration source.



## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

**Box III**

PCT Rule 39.1(iv) - Method for surgical treatment of the human or animal body

**Box IV (continued)**

Devices of this type are already known; cf. US-A-5456686. Since the common features are already known, they cannot be regarded as "special technical features" pursuant to PCT Rule 13.2.

The (possible) "special technical features" of the subject matter of the first group of inventions consist in that an amplitude/direction changing element is provided.

The (possible) "special technical features" of the subject matter of the second group of inventions consist in that:

energy flow guides are provided that are shaped like points (claim 19) or edges (claims 21 and 22), the energy flow guides being at a distance of 2 to 5 mm from each other.

Since there is no technical relationship between these groups of claims, and since different problems are being solved, unity of invention cannot be established.